DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 18,2014

American I.V. Products, Inc. dba AIV, Inc.
Ms. Shannon Houchen
QA Manager
7485 Shipley Avenue
Harmans, MD 21077

Re: K142333
Trade/Device Name: Smart Label, Propofol
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MRZ
Dated: November 14, 2014
Received: November 19, 2014

Dear Ms. Houchen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142333

Device Name
Smart Label for Propofol

Indications for Use *(Describe)*

The Smart Label for Propofol is intended for controlled rate delivery of small volume parenteral fluids when used with the InfusO.R. Pump. The Smart Label is intended for use with Propofol as indicated on the label at the specified concentration for delivery using the syringe size also indicated on the Smart Label.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K142333

Device Name

AIV Device Name: **Smart Label for Propofol**
Classification Name: Accessory to Infusion Pump
Common Name: **Smart Label for Infusion Pump**

Applicant

American IV Products, Inc.
7485 Shipley Avenue
Harmans, MD 21077

Submittal Date

November 14, 2014

Contact Name

Dr. Mark Walter
Director of Engineering
(410)787-1300 Ext. 131

Establishment Registration Number

1121996

Device Classification

Device Regulation Number: 21 CFR 880.5725

Regulation Name: Pump, infusion

Class: Class II

Product Code: MRZ - Accessories, pump, infusion

Applicable Panel: General Hospital

514 Performance Standards

None established under section 514

Prescription Status

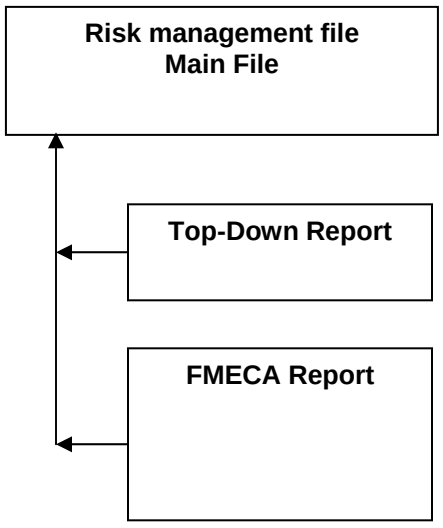
The subject devices are a prescription device.

Compliance to Standards and Regulations

None

Summary of Risk Management Process

The risk management file was used throughout the development process. This file consists of three sections:



- Determination of intended use and characteristics
- Identification of the possible hazards
- Risk assessment and evaluation system
- Residual risk evaluation

- Evaluation of possible hazards and its potential cause,
- Assessment of the risks posed by the hazards,
- Description of the risk management methods that shall be employed for each identified hazard while design phase

- Identification of the safety-related components
- Ranking of the effects of single component failures
- Description of the mitigation techniques to reduce the potential hazard

Reason for Submission

This is a new device to be marketed by our firm.

Labeling

Proposed labeling is provided in Section C.

Statement of Indications for Use

The Smart Label for Propofol is intended for controlled rate delivery of small volume parenteral fluids when used with the InfusO.R. Pump. The Smart Label is intended for use with Propofol as indicated on the label at the specified concentration for delivery using the syringe size also indicated on the Smart Label.

AIV Part #	Description
BX12812	Smart Label, Propofol

Product Description

AIV's **Smart Label for Propofol** is a replacement for the Smart Label manufactured by the Original Equipment Manufacturers (OEM) for the InfusO.R. pump. AIV does not manufacture the pump. The **Smart Label for Propofol** is an accessory for the pump and is also available as a replacement part.

The AIV **Smart Label for Propofol** uses the same type of construction and has the same technological characteristics as the predicate device – the accessory supplied with the InfusO.R. pump. This device is not a kit and does not contain any electronic components. Construction of this device is substantially equivalent to the predicate device.

AIV **Smart Label for Propofol** is not intended to make contact with the patient.

The AIV **Smart Label for Propofol** is limited by the indications for use of the InfusO.R. pump.

Section E contains product specification drawings.

Principle of Operation

The **Smart Label for Propofol** is a magnetic label that attaches to the front label of the pump. It has 2 main functions – to display to the user the values of each switch setting and for the pump to properly recognize the label and apply in its internal calculations the data table corresponding to those label values. On the face of the labels are numeric values that the user (healthcare provider) uses to select the available options through the rotary dial selection process. The Smart Label is also magnetically coded with individual magnets to allow the InfusO.R. pump through an internal bank of hall effect sensors, to recognize which label is applied and to select the internal data table corresponding to that label and set the delivery rate per the label and the rotary switches on the pump as set by the user. The output of the hall effect sensors is a digital value. Only a subset of the possible outputs of the hall effect sensors is valid. On power up, the pump displays the code of the detected label on the pump's LCD display. The pump conducts the necessary calculations required to deliver the drug as indicated on the respective label and the location of rotary switch settings as set by the health care provider.

Proposed Conditions of Use

The **Smart Label for Propofol** is to be used with the InfusO.R. pump. They are to be applied to the pump by a biomedical technician or patient care provider knowledgeable in the operation of the pump. The pump is then used according to its specific conditions of use. No interaction is expected with other devices or with the patient.

Predicate Device Information

This AIV device is Substantially Equivalent to the accessory available with/for the following legally marketed devices:

C.R. BARD, INC. K883577

Substantial Equivalence Comparison Chart

AIV		**Bard (Baxter)**
Intended Use	This device is an accessory and a replacement part for a pump (not manufactured by AIV, Inc.). The healthcare provider applies the device to the pump. The pump will recognize the label applied and adjust the delivery rate per the label and the rotary switches on the pump as set by the healthcare provider. The pump conducts the necessary calculations required to deliver the drug as indicated.	Same
Indications for Use	The Smart Label for Propofol is intended for controlled rate delivery of small volume parenteral fluids when used with the InfusO.R. Pump. The Smart Label is intended for use with Propofol as indicated on the label at the specified concentration for delivery using the syringe size also indicated on the Smart Label.	Same
Operating Principle	Numeric Values on label convey to the healthcare provider the value of the rotary switch settings. Magnetic coding of Smart Label allows the InfusO.R. pump through the use of a bank of internal hall effect sensors to recognize which label was applied to the pump and to select the internal data table corresponding to those settings.	Same

Technology	Magnetic label that allows for attachment to the pump. They are also magnetically coded with individual magnets.	Same
Performance Features	Dose Units, Dose/Delivery Accuracy	Same
Health Care Provider Settings	No configuration settings available for customization on the Smart Label. All the settings are entered in the InfusO.R. pump.	Same
Size	L 5.950" X W 2.315" X H 0.065"	Same
Material	Ferrite Bonded with Synthetic Rubber	Same
Functions	To display to the user the values of each switch setting and for the pump to properly recognize the Propofol label and apply in its internal calculations the data table corresponding to the Propofol label values	Same
Shelf Life	Shelf life and expiration are not required as the pump will provide an indication when the Smart Label applied is not recognized. This will cause the pump to produce an error message thus failing to a safe state. This finding is detailed in our report titled "Analysis of Weak or Missing Magnet". The devices were subjected to repeated cleaning cycles prior to testing – the process and findings are detailed in the report titled "Cleaning and Storage Tests".	
Cleaning & Disinfection	The devices were subjected to repeated cleaning cycles prior to testing – the process and findings are detailed in the report titled "Cleaning and Storage Tests".	Same

Reports characterizing the predicate device are included in Section H. The engineering drawings specifying the AIV product are in Section E.

Performance, General Safety and Effectiveness

AIV's device in this submittal is only the **Smart Label for Propofol** and is only intended as a replacement for the OEM accessory for the InfusO.R. pump. Performance criteria of the label are the label content and the recognition of the Propofol label by the pump. The pump adjusts the delivery rate per the applied label and the rotary switches on the pump as set by the user. Once proper content of the Propofol Smart Label is confirmed and proper detection of the label by the pump is established, accuracy of measurement is a function of the InfusO.R. pump. The AIV **Smart Label for Propofol** is limited by the indications for use of the InfusO.R. pump.

The following non clinical test protocol was identified for the AIV **Smart Label for Propofol** model:

1. Verification Testing – Construction, material selection, content and operation consistent with the technical specifications, proper recognition of the label by the pump.

2. Storage and Cleaning Tests – Subjecting the Smart Label to repeated cleaning cycles and to storage environmental limits and confirming that operation remains consistent with the technical specifications – legibility to user and proper recognition by the pump.

3. Performance Testing – A test protocol was developed to confirm proper recognition and delivery dosage consistent with the predicate device and the technical specifications of the InfusO.R. pump.

Testing was performed by AIV at their facility in Harmans, MD. All test reports are in Section F.

Because of the extreme similarities of the AIV product to the OEM, the consequences of a modified device are the same for both AIV and OEM devices. Also, because of these extreme similarities, the consequences of a device failure are the same for both AIV and OEM devices.

A risk management file was developed and used throughout the development process – please see Section G.

Device Shelf Life / Expiration Date / Aging

Shelf life and expiration are not required as the pump will provide an indication when the

Smart Label applied is not recognized. This will cause the pump to produce an error message thus failing to a safe state. This finding is detailed in our report titled “Analysis of Weak or Missing Magnet”. The devices were subjected to repeated cleaning cycles prior to testing – the process and findings are detailed in the report titled “Cleaning and Storage Tests”.

EMC and Electrical Safety Evaluation

The devices do not contain any electrical or electronic components. The magnets on the labels activate a bank of hall effect sensors in the pump. Since we are using substantially equivalent magnets, the effect on the pump of any electromagnetic interference is not altered. No EMC or Electrical Safety Evaluation is required.

Clinical Testing

No clinical testing was performed for these devices.

Conclusion

The non clinical testing has demonstrated that the AIV **Smart Label for Propofol** is as safe, as effective, and perform as well as the legally marketed accessories for the InfusO.R. pump. Construction of this device is substantially equivalent to the predicate device.